



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

October 16, 2017

Kurt A. Barwis, FACHE
President and Chief Executive Officer
Bristol Hospital, Inc.
P.O. Box 977
Brewster Road
Bristol, Connecticut 06011-0977

**SUBJECT: BRISTOL HOSPITAL, INC. - NRC INSPECTION NO. 03001249/2017001 AND
NOTICE OF VIOLATION**

Dear Mr. Barwis:

This letter refers to the inspection conducted on March 30, 2017, at your Bristol, Connecticut facility. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. Additional information received May 1, 2017, and July 24, 2017, was also examined as part of the inspection. A telephonic exit meeting was held with Mr. Al Lamprey and other members of your staff on October 3, 2017. During the exit meeting, you committed to further revise your brachytherapy treatment policy to include the following statements: In case seeds are unintentionally implanted into another named structure, excluding the urethra, which is not included in the post-treatment planning, and excluding structures intentionally implanted outside of the prostate including prostatic capsule, peri-prostatic tissue and seminal vesicles, we will evaluate the structures dosimetrically and review the case with the Radiation Safety Committee. Any cases meeting the criteria in the 10 CFR 35.3045 will be reported to the NRC, as required.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violation(s) of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at (<http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>). The violations are cited in the enclosed Notice of Violation (Notice) because the violation was identified by the NRC.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket and include: (1) the written directive for prostate brachytherapy, after implantation, but before completion of the procedure, was revised to include the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose) in accordance with 10 CFR 35.40(b)(6)(ii); and (2) a 10 CFR 35.300 authorized user was added to the Radiation Safety Committee in accordance with 10 CFR 35.24(f). Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position.

In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Current NRC regulations and guidance are included on the NRC's Web Site at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's Web Site at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

If you have any questions regarding this matter, please contact Janice Nguyen of my staff at (610) 337-5006 or via electronic mail at janice.nguyen@nrc.gov.

Thank you for your cooperation.

Sincerely,



Donna Janda, Chief
Medical Branch
Division of Nuclear Materials Safety
Region I

Docket No. 030-01249
License No. 06-02057-01

Enclosure:
Notice of Violation

cc w/ Encl: Stewart E. Bober, M.D.
Radiation Safety Officer
State of Connecticut

K. Barwis

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In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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Thank you for your cooperation.

Sincerely,

/RA/

Donna Janda, Chief
Medical Branch
Division of Nuclear Materials Safety
Region I

Docket No. 030-01249
License No. 06-02057-01

Enclosure:
Notice of Violation

cc w/ Encl: Stewart E. Bober, M.D.
Radiation Safety Officer
State of Connecticut

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SUNSI Review Complete: JNguyen

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OFFICE	RI:DNMS	N	RI:DNMS	N				
NAME	JNguyen <i>JN</i>		DJanda <i>DJ</i>					
DATE	10-3-17		10/16/2017					

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NOTICE OF VIOLATION

Bristol Hospital, Inc.
Bristol, Connecticut

Docket No. 030-01249
License No. 06-02057-01

During an NRC inspection conducted on March 30, 2017, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.40(b)(6)(ii) requires, in part, that a written directive for all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders, include the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose) after implantation, but before completion of the procedure.

Contrary to the above, as of March 30, 2017, the written directive for all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders, did not include the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose) after implantation, but before completion of the procedure. Specifically, the post implantation written directive did not include the radionuclide, the treatment site, and the total source strength and exposure time (or the total dose).

This is a Severity Level IV violation (Enforcement Policy Example 6.3.d.1.).

Corrective actions included modifying the written directive to include all required elements.

- B. 10 CFR 35.24(f) requires, in part, that licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H, of this part, shall establish a Radiation Safety Committee (RSC) to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user (AU) of each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an AU nor a RSO.

Contrary to the above, as of March 30, 2017, Bristol Hospital, Inc.'s RSC did not include an AU of each type of use permitted by the license. Specifically, the RSC did not include a 10 CFR 35.300 AU.

This is a Severity Level IV violation (Enforcement Policy Example 6.3.d.3.).

Corrective actions included appointing a 10 CFR 35.300 AU to the RSC.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated This 16th day of October 2017